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Title of the Invention

SURGICAL TOOLS

Field of the Invention

This invention generally relates to surgical tools and more specifically to tools and a method used for implanting medical devices within bone.

Background of the Invention

Injury to the spinal cord of humans and animals has been known to cause paralysis. However, muscle movement may still be achieved by direct electrical stimulation to the muscle. Stimulation has been provided in humans and animals using various electrical stimulation devices are known to provide such muscle movement. For example, U.S. Patent No. 5,167,222 discloses a well known functional neuromuscular stimulation system. Such systems typically include a implantable stimulator telemeter devices (IST). The IST is powered through a transcutaneous radio-frequency link which also controls the IST from an external control unit. Wires run from the IST to various muscles of the body which are to be stimulated.

However, to optimize the usage of an IST it is important to obtain feedback information regarding muscle movement. Thus, a sensor, or sensor system, which may detect the relative motion between bones or muscles is used. A common type of sensor system is a combination of a magnet and a magnetic field (Hall Effect) sensor. The Hall Effect sensor can detect motion of the magnet and can send an electrical signal to a processor. The electrical signal can be used to control the actions of the IST.

Tools exist for placing simple attachments onto bones. For example, a miniature screwdriver may be used to insert bone screws into bones. The situation is more complex however when the elements to be implanted are a sensor system including magnets. Electrical leads typically extend from an end of the sensor. Thus, common insertion tools which mate with the end of an element cannot be used. A cannulated or tubular device must be used. Cannulated drills and taps have been used in the area of orthopedic fracture treatment. However, these tools are not adapted for the process of implanting delicate transducer devices of the type disclosed in U.S. Patent No. 5,167,229.

Improved tools and a method for inserting sensor systems with magnets using these tools is desired.

Summary of the Invention

The present application provides improved surgical tools, a surgical tool set, and an improved method for use in implantation of a medical device into living bone.

The improved tool set allows small and delicate medical devices to be implanted into living bone.

Further, use of the improved tool set and method allows devices to be implanted into living bone without substantially disturbing the surrounding tissue.

Further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description.

Brief Description of the Figures

FIG. 1 is a schematic view of two bones within which an Implantable Joint Angle Transducer is implanted;

FIGS. 2 top view of a tool set;

FIG. 3 is schematic view of a fork shaped jig and drill guide tools shown adjacent the bones to be implanted;

FIGS. 4A and 4B are side and top views, respectively, of a centering jig tool;

FIGS. 5A-5C are top, side, and end views, respectively, of a cannulated tap;

FIGS 5D and 5E are top and side views of the portion of the cannulated tap cut-away in Figures 5A and 5B respectively.

FIGS. 6A-6J illustrate various views of components of a magnet insertion tool;

FIGS. 7A-7 are top, side, cut-away side and end views of a sensor insertion tool;

FIG. 8 is a schematic illustration of the magnet system to be implanted using the tool set of the present application;

FIG 9 is a schematic illustration of the sensor systems to be implanted using the tool set of the present application;

FIG 10 illustrates the bones to be implanted using the tool set of the present application where an incision may be made along the dashed lines I in the covering tissue to expose the bones;

FIG 11 schematically illustrates a step of the method of the present application using the centering jig tool;

FIG 12 schematically illustrates a step of the method of the present application including drilling and tapping of a first bone to be implanted;

FIG 13 schematically illustrates a step of the method of the present application including drilling and tapping of a second bone to be implanted;

FIG. 14 schematically illustrates a step of the method of the present application including insertion of a sensor system into a second bone; and,

FIG 15 schematically illustrates a step of the method of the present application including insertion of a magnet system into a first bone using a magnet insertion tool of the present application.

Detailed Description of the Preferred and Alternate Embodiments

Implantable Joint Angle Transducers (IJAT) are used to obtain information in an electronic form. This information relates to the relative motion between muscles or bones. The IJAT are implanted into living bone as shown in FIG. 1. Described below are innovative tools for implanting IJAT into living bone and a method of implantation using these tools.

Tools

Referring to the drawings, FIGS. 2 and 3 illustrate a preferred tool set 50 according to the invention. The tool set 50, as described in more detail below, includes two or more guide wires 52, a centering jig 70, a screwdriver handle 80, one or more cannulated drills 90, one or more cannulated taps 100, a T-handle 110, a magnet insertion tool 120, a sensor insertion tool 170, and a

forked shaped jig 190. The tool set 50 is used to implant a medical device in adjacent living bones. The illustrated bones are the radius R and the lunate L in a human wrist joint. The medical device illustrated includes a first portion which is a magnet system 200 and a second portion illustrated as a sensor system 250 as illustrated. The first portion 200 of the medical device is implanted in the lunate L bone. The second portion of 250 of the medical device is implanted in the radius R bone.

Included in the tool set 50 are one or more guide wires 52. The guide wires 52 are attached to the bone in a desired location. The guide wires 52 then are used to guide the cannulated drills 90 and cannulated taps 100 to the desired location on the bone. The guide wire 52 is preferably thin and has a threaded end. The guide wire 52 is also resilient and will not kink even when bent at extreme angles. Preferably the guide wire 52 is metallic, however it may be made of any material which is easily distinguishable on an X-Ray image.

Included in the tool set 50 is a centering jig 60 shown in detail in FIG 4. The centering jig 60 is uniquely designed for the process of implantable joint angle transducer 30 implantation. The centering jig 60 is used as a guide for placing the guide wire 52 into contact with the bone. The centering jig 60 includes an elongate shaft 62, neck 68 and head 74. The elongate shaft 62 has a first end 63 and a second end 64. The first end 63 is machined in order to be attachable to the screwdriver handle 80 or T-handle 110. The second end 64 is attachable to the neck 68. The elongate shaft 62 and neck 68 are oriented along a common line. The elongate shaft 62 is attached to the neck 68 using a pin, but a screw, force fit, weld or similar means may also be used. The neck 68 has a

diameter, a first end 69 and a second end 70. The second end 70 is attached to the head 74. The position of the head 74 is angled with respect to the line upon which the neck 68 and elongate shaft 62 lie. Preferably the second end 70 is threaded and screws into the head, but a force fit, weld or similar means may also be used. The head 74 is hollow and has a first end 75, a second end 77 and a middle 76. In a preferred embodiment the outer diameter of the head 74 is equal to the outer diameter of the magnet capsule 202. In an alternate embodiment, the outer diameter of the head 74 may be any diameter. Preferably the middle 76 of the head 77 is attached to the neck 68. The first end 75 of the head 74 is equipped with a plurality of teeth 78. The teeth 78 are able to adhere to bone. The guide wire 52 may be passed through the hollow head 74. Preferably the centering jig 60 is made of stainless steel, however it may be made of any material which is easily distinguishable on a X-Ray image.

The tool set 50 includes one or more cannulated drills 90. The bore size of the cannulated drills 90 may vary. The cannulated drills 90 are hollow and may consist of varying bore sizes. Each cannulated drill 90 has a first end 91 and second end 92. The first end 91 is attachable to a handle 82 and the second end is fluted.

The tool set 50 includes one or more cannulated taps 100 as shown in detail in FIG. 5A-5E. The cannulated taps 100 are hollow and may consist of varying thread sizes. Each cannulated tap 100 has a first end 101 and second end 102. The first end is attachable to a handle 82. The second end 102 has four longitudinal flutes 103 and is threaded.

The tool set 50 includes a magnet insertion tool 120 as shown in detail in FIGS. 6A-6K. The magnet insertion tool is able to hold the magnet capsule 202 while allowing rotation of the magnet capsule 202 in either a clockwise or counter clockwise direction. The magnet insertion tool 120 is comprised of a collet 130, a center shaft 122, an outer shaft 140, a locking shaft 150, and a rotating handle 160. The magnet insertion tool 120 is able to release the magnet capsule 202 by simply moving the rotating handle 160. The collet 130 as shown in FIGS 6A, 6B, 6J, and 6K has a circular cross section, an exterior surface 133 and a first end 131 and second end 132. The first end 131 is hollow, having an outer sleeve 134, which has an outside surface 135. The outer sleeve 134 is expandable in order to hold and release the magnet capsule 202. The first end 131 is flared and the outer sleeve 134 is comprised of a plurality of tines 136. When expanded, open space appears between the tines 136. When contracted, each tine 136 abuts an adjacent tine 136. One tine 136 includes an aperture 137. An alignment pin 138 may be seated within the aperture 137 and when seated extends into the interior of the outer sleeve 134. The alignment pin 137 may be used to align the magnet capsule 202 when the magnet capsule 202 is held within the outer sleeve 134. The second end 132 of the collet 130 is attachable to the center shaft 122. The collet 130 may be attached to the center shaft 122 using a pin, screw, force fit, weld or similar means. Preferably the collet 130 is made of stainless steel, however it may be made of any material which is easily distinguishable on a X-Ray image.

The center shaft 122 as shown in FIGS 6C-6E is elongated and has a first end 123 and second end 124. The first end 123 is attached to the collet 130

while the second end 124 is attached to the locking shaft 150. Preferably the center shaft 122 is attached to the locking shaft 150 with a set screw.

The outer shaft 140, as shown in FIG 6F, is elongated and has a first end 141 and second end 142. The outer shaft 140 is hollow and may slide along the exterior surface of the center shaft 122. Upon sliding the outer shaft 140 acts as a ferrule, opening and closing the multiple tines 136 of the collet 130. The first end 141 of the outer shaft 140 is chamfered in order to allow smooth contact with the exterior surface of the outer sleeve 134. The first end 141 of the outer shaft 140 may be pushed against the exterior surface of the outer sleeve 134, thus forcing the tines 136 together. The first end 141 of the outer shaft 140 may also be pulled away from the exterior surface of the outer sleeve 134, thus allowing the tines 136 to expand. The second end 142 of the outer shaft 140 is flared outwardly allowing the outer shaft 140 to abut against the rotating handle 160.

The locking shaft 150 as shown in FIG 6H, is elongated and has a first end 151, a second end 153 and a central nub 152. The locking shaft 150 is hollowed from the first end 151 partially through the central nub 152. The center shaft 122 may be inserted into the hollowed area of the locking shaft 150 and attached using a set screw. The first end 151 of the locking shaft 150 is threaded for attachment to the rotating handle 160. The second end 153 is attachable to a handle 82.

The rotating handle 160 as shown in FIG 6G, is a hollow shaft having a first end 161, a second end 162, and an outside surface 163. The outside surface 163 may be knurled. The second end 162 contains an internal thread and is

movably attached to the locking shaft 150. The first end 161 abuts the outer shaft 140. Upon rotation of the rotating handle 160 on the internal threads, the rotating handle 160 forces the outer shaft 140 to move towards or away from the collet 130.

The collet 130, center shaft 122, outer shaft 140, locking shaft 150, and rotating handle 160 are all preferably made from stainless steel.

The tool set 50 also includes a sensor insertion tool 170, as shown in FIGS 7A-7D. The sensor insertion tool 170 is a shaft including a first end 171, second end 173, trough 172, and a keyed portion 174. The second end 174 is attachable to a handle 82. The keyed portion 174 is at the first end 171 of the sensor insertion tool 170 and the trough 172 is adjacent to the keyed portion 174. The trough 172 is formed of two arched sides 175 and 176 and has a C-shaped cross section and acts as a holder for the leads 256 from the sensor system 250. The keyed section 174 comprises two prongs 177 and 178 which are partial longitudinal extensions of the sides 175 and 176 of the C-shaped trough 172. The keyed section 174 may be any shape but is preferably T-shaped when viewed perpendicularly to the longitudinal line of the sensor insertion tool 170. The keyed section 174 mates with oval slots 258 upon the sensor system 250 and attaches to the sensor system 250. The top of the T-shaped keyed portion 174 will slide side to side without detachment within the oval slot 258 depending upon the direction of rotation of the sensor system 250 and sensor insertion tool 170. The sensor system 250 may be detached from the keyed portion 174 when the keyed portion 174 is slid to the center of the oval slot 258 and pulled longitudinally away from the sensor system 250.

The centering jig 60, cannulated drill 90, cannulated tap 100, magnet insertion tool 120 and sensor insertion tool 170 are all attachable to a handle 82. The handle 82, as shown in FIG. 2, can be any type of handle such as a screwdriver handle 80 or a T-handle 110. The above mentioned tools are also attachable to other implements such as drills, clamps, or robot arms.

The tool set 50 includes a fork jig 190 as shown in FIG. 3. The forked jig 190 is used in combination with a drill guide 198 to direct a guide wire 52 to a bone. The forked shaped jig 190 is a solid having a base 191 and two prongs 192 and 193. The base 191 has a front surface 194 and a back surface 195 and multiple apertures 196 which pass from the front surface 194 to the back surface 195. The prongs 192, 193 are parallel and extend vertically away from the base 191. One guide wire 52 may pass through one on the apertures 196 then allowing placement of a second guide wire 52" within a certain distance from the first guide wire 52'. A slot 197 having a width exists between the two prongs 192, 193. A tubular drill guide 198 having a width less than or equal to the width of the slot 197 is used to direct a guide wire 52 to bone. The tubular drill guide 197 is placed between the two prongs 192, 193 of the forked shaped jig 190.

The Device To Be Implanted

The tool set 50 is used to implant a medical device in living bone. The device illustrated includes the elements of an implantable joint angle transducer (IJAT) 30. The IJAT 30 is mounted to adjacent bones and is able to sense relative motion. The sensed motion is translated into an electrical signal which is sent by leads 256 to the Implantable Stimulator Telemeter or another device

which can process data. The IJAT 30 includes a first portion of the medical device, or a magnet system 200 and a second portion of the medical device or sensor system 250, as seen in FIG. 8 and FIG. 9, respectively. As described in more detail below, the magnet system 200 includes a permanent magnet 201 (not shown), a magnet capsule 202 and a capsule lid 203. As described in more detail below the sensor system 250 includes one or more sensors 251 (not shown), a sensor capsule 252, a strain relieving sleeve 253 and sensor leads 256.

Included in the magnet system is a permanent magnet 201. The permanent magnet 201 may be any shape, but is shown as a cylindrical solid. The permanent magnet 201 is made of Neodymium-Iron-Boron, but may be any magnetic material. The magnet system 200 includes a magnet capsule 202. The permanent magnet 201 is held within the magnet capsule 202. The magnet capsule 202 is preferably a hollow cylinder having a circular cross section. The magnet capsule 202 has an outside surface 204 which is threaded with a pitch of 32 threads per inch. The leading edge 205 of the magnet capsule is not threaded. One or more longitudinal grooves 206 are cut through the threads on the outside surface 204 for the passage of liquids. The thread size matches the thread size of the cannulated tap 100. Preferably the magnet capsule 202 is made of titanium. The magnet capsule 202 is simply screwed into place within a bone which has previously been drilled and tapped. The magnet system 200 further includes a magnet capsule lid 203. The magnet capsule lid 203 is preferably a cylindrical solid with a flanged end. The capsule lid 203 further includes an exterior surface which is slotted and which is placed inside of the

magnet capsule 202 The flanged end of the magnet capsule lid 203 can be easily gripped by the magnet insertion tool 120.

The sensor system 250 is placed adjacent to the magnet system 200 and senses the magnetic field of the permanent magnet 201. The sensor system 250 includes a sensor capsule 252 which is a hollow cylinder with a closed end. Preferably the sensor capsule 252 is made of titanium. The sensor capsule 252 has an outside surface 254 which is partially or completely threaded. Any thread pitch may be used, but a pitch of 14 threads per inch is preferred. One or more longitudinal grooves 255 are cut through the threads on the outside surface for the passage of liquids. The sensor capsule 252 also has two oval slots 258 with longitudinal stems on the outside surface 254. The oval slots 258 mate with the keyed portion 174 of the sensor insertion tool 170. When centered within the oval slot 258, the keyed portion 174 of the sensor insertion tool 170 may be withdrawn through the slot's longitudinal stem. The sensor system 250 also includes one or more sensors 251. Preferably the sensors 251 are one or more Hall Effect sensors in combination with a Hittman hexapolar feedthrough.

Data from the sensors 251 is transmitted to a device electronically through sensor leads 256. The leads 256 are preferably common shielded cables. The sensor system 250 includes a strain relieving sleeve 253 to protect the sensor leads 256. The strain relieving sleeve 253 is a hollow tube which surrounds all leads exiting the sensor capsule 252. The strain relieving sleeve 253 prevents damage to the leads 256 by allowing limited bending of the individual leads 256. The strain relieving sleeve 253 is bendable but resilient.

METHOD

IJAT systems 30 are implanted into bones. For test purposes the IJAT system 30 may be inserted into a non-living bone. IJAT systems 30 are implanted into living human or animal bones. The IJAT system 30 is used in conjunction with an implantable stimulator telemeter, but may be used by itself as well. A method for inserting an IJAT system 30 into living bone is described below. Also described is a one embodiment of the method where the IJAT 30 is being inserted into the lunate and radius bones of the human wrist.

The process of inserting an IJAT 30 is performed utilizing fluoroscopy so the surgeon performing the insertion may be able to view all tools as well as the IJAT 30. Depending upon the step being performed in the method, the fluoroscopic views may be in a single plane or bi-planer. In one embodiment, fluoroscopy is performed using a radio-lucent hand table.

The first step, as shown in FIG 10, in the IJAT 30 insertion method is to create an incision in the skin surrounding the bone into which the IJAT 30 will be inserted. In one embodiment of the method the incision is made from the capito-lunate joint to the radio-carpal joint.

The second step in the IJAT 30 insertion method is to expose the bone into which the IJAT 30 will be inserted. Dissection is kept to a minimum in order keep blood providing arteries functional. In one embodiment, the lunate bone is exposed just proximal to its dorsal pole. In one embodiment the radius bone is exposed from a point approximately one inch proximal to the wrist joint.

The third step 30, as shown in FIG. 11, in the IJAT insertion method is placement of the centering jig 60 over the first living bone. In one embodiment

of the method, the first living bone is the lunate bone of the wrist. The teeth 78 upon the head 74 of the centering jig 60 are placed in contact with the first living bone. The centering jig 60 is located in the appropriate position by a surgeon who is able to view the centering jig 60 by fluoroscopy. In one embodiment of the method, the appropriate position is achieved when the lunate bone is visible all around the circle created by the head 74 of the centering jig 60. In one embodiment the head 74 of the centering jig 60 has a length of 0.787 inches and a diameter of 0.177 inches.

The fourth step in the IJAT 30 insertion method is the insertion of the first guide wire 52' into the first living bone. The first guide wire 52' is fed through the hollow head 74 of the centering jig 60. The first guide wire 52', being threaded, may be engaged with the first living bone L. In one embodiment, the first guide wire 52' is 154 millimeters long and has a diameter of 2 millimeters. A benefit to placing a guide wire 52' is that if the surgeon determines the placement of the guide wire 52 is not appropriate, relocation may be performed without excessive trauma and with minimal damage to the living bone. In one embodiment of the method the first guide wire 52' is placed into the dorsal surface of the lunate bone.

The fifth step in the IJAT 30 insertion method is the removal of the centering jig 60. The sixth step, as shown in FIG 3, in the IJAT 30 insertion method is the placement of the fork shaped jig 190. The first guide wire 52' is threaded through one of the apertures 196 in the base 191 of the fork shaped jig 190. Placing the first guide wire 52' within the fork shaped jig 190 guarantees that the second guide wire 52" will be located within a desired distance of the

first guide wire 52'. The seventh step in the IJAT 30 insertion method is the placement of a drill guide 198 within the slot 197 of the fork shaped jig 190. The eighth step in the IJAT 30 insertion method is the placement of the second guide wire 52. In one embodiment, the second guide wire 52" is 154 millimeters long and has a diameter of 2 millimeters. The second guide wire 52" is threaded through the drill guide 198 and engaged with the second living bone R. In one embodiment of the method the second guide wire 52" lodges in subchondral bone midway between the dorsal and volar cortices.

The ninth step as shown in FIG. 12 in the IJAT 30 insertion method is the drilling of the first living bone L. A cannulated drill 90, which circumscribes the first guide wire 52' is used to drill the first living bone L. In one embodiment of the method a 4.5 mm drill is used and the drilling depth does not exceed ten millimeters. In one embodiment, only lateral fluoroscopy is necessary for viewing the drilling process. The tenth step in the IJAT 30 insertion method is the removal of the cannulated drill 90 and the tapping of the drilled hole. Tapping is performed using a cannulated tap 100 which circumscribes the first guide wire 52". The cannulated tap 100 is driven to the depth to which the hole was drilled. In one embodiment, a 5 millimeter cannulated tap is used. The eleventh step in the IJAT insertion method is the removal of the first guide wire 52" while leaving the cannulated tap 100 in place.

The twelfth step, as show in FIG 13, in the IJAT 30 insertion method is the drilling of the second living bone R. A second cannulated drill 90' which circumscribes the second guide wire 52" is used to drill a hole in the second

living bone R. In one embodiment of the method, the hole is drilled in multiple stages to avoid having the drill bit walk. The drilling is performed with a 4.5 millimeter drill, followed by a 6.5 millimeter drill and an 8 millimeter drill is used to overdrill only the cortex portion of the second living bone R. The thirteenth step in the IJAT 30 insertion method is the removal of the second cannulated drill 90' and the tapping of the drilled hole. Tapping is performed using a second cannulated tap 100' which circumscribes the second guide wire 52". In one embodiment of the method a 6.5 millimeter cannulated tap is used. The second cannulated tap 100' is driven to the depth to which the hole was drilled.

The thirteenth step in the IJAT 30 insertion method is the removal of the second cannulated tap 100' and the second guide wire 52" and the insertion of the sensor system 250, as shown in FIG. 14. The sensor system 250 is attached to the sensor insertion tool 170. The sensor system 250 is then threaded into the tapped hole in the second bone R. Once in position the keyed section 174 of the sensor insertion tool 170 is centered within the oval slot 258 upon the sensor capsule 252 and the sensor insertion tool 170 is detached. The fourteenth step in the IJAT 30 insertion method is to electrically connect the sensor leads 256 to the implantable stimulator telemeter or other device.

The fifteenth step in the IJAT 30 insertion method is the removal of the cannulated tap 100 from the hole in the first living bone L and the insertion of the magnet system 200, as shown in FIG. 15. The magnet system 200 is implanted using the magnet insertion tool 120. The magnet system 200 is placed into a desired position as determined by feedback from the sensor 251

and the implantable stimulator telemeter or other device. The axis of the permanent magnet 201, which runs perpendicular to a long axis of the magnet capsule 202, is oriented with either north or south facing the sensor 251 to get the signals form the sensor 251 as close to the center of a 12 bit AD range as possible.

Although the device and method have been shown and described with reference to certain embodiments minor variation and insubstantial differences in the various combination of materials and methods of application may occur to those of ordinary skill in the art while remaining within the scope of the invention as claimed and equivalents.